

### REMARKS

This document is filed in reply to the office action dated July 22, 2004 ("Office Action"). Applicants have amended claims 2-6 to promote clarity and to correct informalities. No new matter has been introduced.

Claims 1-16 are pending and under examination. Reconsideration of this application is requested in view of the following remarks:

#### Objection to the Specification

The Examiner objected to the Specification, contending that "[t]he specification contains sequence disclosures that are not identified by SEQ ID NO[s] (e.g., page 14, lines 24-25 and page 15, lines 16-17)." See the Office Action, page 3, second paragraph.

Applicants disagree. The two passages of the Specification at issue disclose four PCR primers, i.e., (i) aagctcatga ttggcagcca gtctccgggc; (ii) gacctcatga accgtcgcta gcgacacgcc; (iii) ttaacgatcg ttagaagcaa acttaagagt g; and (iv) ttaacgatcg atgtaatcac tccttct. They, as well as other sequences disclosed in the Specification, are identified by SEQ ID NOs. See the sequence listing submitted with Applicants' response mailed April 22, 2002. For this reason, Applicants request that the objection be withdrawn.

#### Objection to claims 2 and 4-6

The Examiner objected to claims 2 and 4-6 for containing informalities. Applicants have corrected the informalities, and submit that the objection has been overcome.

#### Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejected claim 3 as being indefinite. See the Office Action, page 5, last paragraph. Applicants have amended this claim in the manner suggested by the Examiner, thereby overcoming the rejection.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected claim 13, 15, and 16 under § 112, first paragraph on two grounds.

Applicants traverse each below:

I

Claim 13, drawn to a DNA immunogenic composition, was rejected for lack of enablement. More specifically, it is the Examiner's position that he "can find no asserted use for an immunogenic composition according to the claims other than as a vaccine ... the disclosure fails to provide enablement for the broad scope of immunogenic composition comprising an antigenic gene, wherein said immunogenic compositions are useful as vaccines" See the Office Action, page 3, first paragraph.

Applicants disagree. Indeed, the Specification clearly teaches a number of uses of the claimed composition. For example, the composition, which contains a Lac shuttle vector, allows one "to express a heterologous gene in an organism or as a DNA vaccine or health food." See, e.g., the Specification, page 2, lines 11-15; and page 24, lines 15-18. In other words, the claimed composition has utilities other than vaccination. Further, the Specification provides sufficient teachings as to how to make and use the claimed composition. Thus, claim 13 meets the enablement requirement.

II

Claims 15 and 16, covering a Lac shuttle vector and a composition containing the vector, were rejected for containing new matter. The vector includes a nucleic acid encoding "a protein consisting essentially of the sequence of the Rep A protein." According to the Examiner, "the originally filed application and claims do not disclose a sequence for the Rep A protein." See the Office Action, page 5, second paragraph.

Applicants disagree and note that the Specification teaches such a sequence, e.g., a "Rep A protein ... of 317 amino acids." See, e.g., page 7, lines 21-28 of the Specification. In addition, as acknowledged by the Examiner, the just-quoted passage cites several references (e.g., Bouia et al, 1989, Plasmid, 22: 185-192), which disclose nucleic acids encoding the Rep A protein. See, the Office Action, page 2, lines 18-20.

In particular, Bouia et al., as well as the corresponding GenBank record, discloses the above-mentioned 317-amino acid Rep A protein and the encoding nucleotide sequence. See GenBank M31223 (copy attached hereto as "Exhibit A."). As shown in this exhibit, nucleotide (nt) 262-1215 of GenBank M31223 encodes the Rep A protein. In this connection, Applicants would point out that the Specification discloses the same nucleotide sequence, i.e., nt 3198-4151 of SEQ ID NO: 1 (i.e., FIGs. 5A-G) as originally filed. For the reasons set forth above, the Examiner clearly erred in asserting that "the originally filed application and claims do not disclose a sequence for the Rep A protein." To promote clarity, Applicants have amended the Specification to identify the amino acid sequence (SEQ ID NO: 8) and the nucleotide sequence (SEQ ID NO: 7) of the Rep A protein and submitted a copy of a substitute sequence listing.

#### CONCLUSION

Applicants submit that the rejections asserted by the Examiner have been overcome, and that the claims, as amended, define subject matter that is definite and sufficiently described. Allowance of this application is therefore proper, and early favorable action is solicited.

Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 9-22-04

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NCBI Nucleotide

Entrez PubMed Nucleotide Protein Genome Structure PMC Taxonomy Books

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Display  Show:

1: M31223. Plasmid pLP1 (from [gi:149684])

LOCUS LP1PLPREP 2093 bp DNA linear BCT 24-APR-1996  
 DEFINITION Plasmid pLP1 (from *Lactobacillus plantarum* CCM 1904) replication protein (rep) gene, complete cds.  
 ACCESSION M31223  
 VERSION M31223.1 GI:149684  
 KEYWORDS replication protein.  
 SOURCE Plasmid pLP1  
 ORGANISM Plasmid pLP1  
 plasmids.  
 REFERENCE 1 (bases 1 to 2093)  
 AUTHORS Bouia, A., Bringel, F., Frey, L., Kammerer, B., Belarbi, A., Guyonvarch, A. and Hubert, J. C.  
 TITLE Structural organization of pLP1, a cryptic plasmid from *Lactobacillus plantarum* CCM 1904  
 JOURNAL Plasmid 22 (3), 185-192 (1989)  
 MEDLINE 90222315  
 PUBMED 2517345  
 COMMENT Original source text: Plasmid pLP1 (tissue library: CCM 1904) DNA.  
 Draft entry and computer-readable sequence for [1] kindly submitted by B. Kammerer, 11-JAN-1990.  
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 RBS 249.. 253  
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 CDS 262.. 1215  
  
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repeat\_region /note="direct repeat M"  
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/note="origin of replication (put.); putative"

ORIGIN 1 bp upstream of HindIII site.

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121 ttggccgctc ggaacacgtg agttgattat catttgcatt ttatagctt ttcagggg  
181 aaaggccat gatgtcaagg tiaataagctt attaaaaaaat atagtcagct ccitcacgt  
241 gataaactgg aggagctttt ttagtcaagg atttttaaag ataaaaactga aatggcaaa  
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1621 ctcacaaacgttactgtgtc gtcagttttgg aacattcaaa aataaataag tttatgtgt  
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2041 tggcgtttgc ttcttatctt gatacttata gcaacaacta gttttttaaa atc

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